JUN 12 2001

510(k) SUMMARY

A. Submitter Information:

Submitter: MEDCOMP®
1499 Delp Drive
Harleysville, PA 19438
(215) 256-4201 Telephone
(215) 256-0818 Fax

Contact: Jeanne M. Cush
Senior Regulatory Affairs Associate

Date Prepared: September 27, 2000

B. Trade Name: Medcomp Ultra-Flow Catheter
Common Name: Hemodialysis Catheter, Implanted
Classification: 78 MSD
C.F.R. Section: 876.5540

C. Predicate Device: K981994 Bard Opti-Flow
K972207 Medcomp Ash Split-Cath

D. Device Description:

The Medcomp Ultra-Flow Catheter is a 14.5F polyurethane, double lumen catheter used to remove and return blood through two-segregated lumen passages. Both lumens are "D" shaped, open at the distal tip, with two side holes. The distal venous lumen is tapered and extends beyond the arterial lumen to reduce recirculation. The fixed polyester cuff allows for tissue ingrowth for long term placement.

The lumens are connected to the extensions via a soft pliable hub with suture wing. The arterial and venous extensions are identified by red and blue luer connectors and clamps. Priming volume information is printed on the clamps for ease in identification.

E. Intended Use:

The Medcomp Ultra-Flow Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein of an adult patient. Alternate insertion site is the subclavian vein as required.

F. Comparison to Predicate Device:

The technological characteristics of the Ultra-Flow are substantially equivalent to the predicate devices in terms of intended use, insertion method, anatomical location, design, materials, performance, labeling, manufacturing process and method of sterilization.

The difference between these devices is the implantable lengths and cuff location.

G. Performance Data:

In Vitro performance data for the Medcomp Ultra-Flow Catheter, including tensile strength, joint strength, leakage, recirculation and flow performance demonstrate that this device is substantially equivalent to legally marketed devices intended for hemodialysis and apheresis treatments.

Clinical studies were not deemed necessary since in-vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 2 2001

Ms. Jeanne M. Cush
Senior Regulatory Affairs Associate
MedComp®
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K003207
Medcomp Ultra-Flow Catheter
Dated: January 22, 2001
Received: January 23, 2001
Regulatory Class: III
21 CFR §876.5540/Procode: 78 MSD

Dear Ms. Cush:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kits and trays have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kits and trays. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used for the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.

2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

In addition, we have determined that your device kit contains Lidocaine HCl, 1%, which is subject to regulation as a drug.

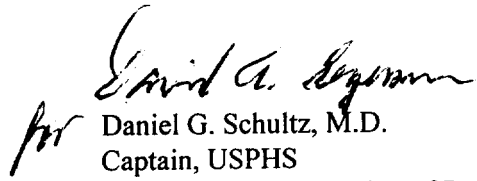
Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR §807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K003207

Device Name: Ultra-Flow Long-Term Hemodialysis Catheter

Indications for use:

THE MEDCOMP ULTRA-FLOW HEMODIALYSIS CATHETER IS INDICATED FOR USE IN ATTAINING LONG-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS.

IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN OF AN ADULT PATIENT.

ALTERNATE INSERTION SITES INCLUDE SUBCLAVIAN VEIN AS REQUIRED.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

David G. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003207

(Optional Format 1-2-96)